Notice of Allowability	Application No.	Applicant(s)	
	09/926,002	SCHRODER ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *20 September 2004*.

2. ☒ The allowed claim(s) is/are *11-50*.

3. ☒ The drawings filed on *13 August 2001* are accepted by the Examiner.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *13 December 2004* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

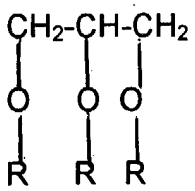
JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Allowance

1. This Office Action is responsive to Applicant's response filed September 20, 2004.

2. All rejections of record are withdrawn in view of Applicant's Amendments and remarks. Claims 11-50 are allowed and have been renumbered as claims 1-40.

3. The following is an examiner's statement of reasons for allowance. The prior art cited neither teaches nor suggests a vaccine formulation nor an aerosol or spray package comprising the vaccine formulation against a *Mycobacterium* comprising an adjuvant comprising: a) monoglyceride preparations having at least 80% monoglyceride content and having a formula



where R is selected from the group consisting of H and an acyl group containing from 6 to 24 carbon atoms with the *proviso* that two of the R groups are H and b) a fatty acid with 6 to 24 carbons atoms and an immunogenic product consisting of antigenically active carbohydrate moieties (ACM) from *Mycobacterium tuberculosis* which are each covalently coupled, via divalent bridge groups to immunologically active carriers (IAC). The instantly claimed vaccine formulation

is novel and therefore, the method of vaccinating a mammal a mammal against *Mycobacterium* as instantly claimed is also novel.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

4. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
December 9, 2004

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Examiner's Amendment

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Richard E. Fichter on December 13, 2004.

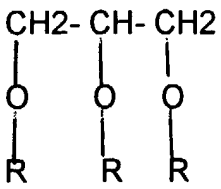
Please Amended the Application as follows:

In the Specification:

The first paragraph of the specification has been amended to include ----- This application claims priority to a 371 of PCT/EP00/01038, filed 09 August 2000. ----.

In the Claims:

11 (currently amended). A vaccine formulation against a *Mycobacterium* comprising ~~as~~ an adjuvant comprising ~~one or more substances selected from the group consisting of:~~ a) monoglyceride preparations having at least 80% monoglyceride content and having a formula

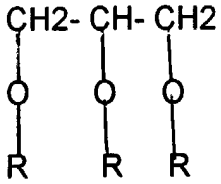


wherein R is selected from the group consisting of H and an acyl group containing from 6 to 24 carbon atoms with the *proviso* that two of the R groups are H and b) a fatty acid with 6 to 24 carbon atoms and ~~as immunizing~~

~~component, and~~ an immunogenic product consisting of antigenically active carbohydrate moieties (ACM) from *Mycobacterium tuberculosis* which are each covalently coupled, via divalent bridge groups, to immunologically active carriers (IAC).

16 (currently amended). The vaccine formulation according to claim 11, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the ~~immunizing component~~ immunogenic component is lipoarabinomannan-tetanus toxoid (LAM-TT).

20 (currently amended). An aerosol or spray package comprising a ~~tuberculosis~~ vaccine formulation comprising ~~as~~ an adjuvant comprising ~~one or more substances selected from the group consisting~~ of: a) monoglyceride preparations having at least 80% monoglyceride content and having a formula



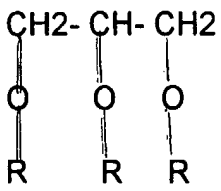
wherein R is selected from the group consisting of H and an acyl group containing from 6 to 24 carbon atoms with the *proviso* that two of the R groups are H and b) a fatty acid with 6 to 24 carbon atoms and ~~as immunizing component,~~ and an immunogenic product consisting of antigenically active carbohydrate moieties (ACM) from *Mycobacterium tuberculosis* which are each

covalently coupled, via divalent bridge groups, to immunologically active carriers (IAC).

22 (currently amended). An aerosol or spray package according to claim 21, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90%, and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms, and the immunologically active carriers (IAC) are ~~derived~~ from polypeptide and are selected from the group consisting of tetanus toxoid, diphtheria toxoid, cholera subunit B and Protein D from *H. influenza.*

25 (currently amended). An aerosol or spray package according to claim 21, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the ~~immunizing component~~ immunogenic product is lipoarabinomannan-tetanus toxoid (LAM-TT).

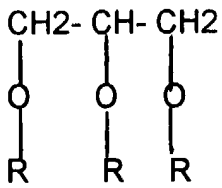
29 (currently amended). A nose-drop package comprising a ~~tuberculosis~~ vaccine formulation comprising ~~as~~ an adjuvant comprising ~~one or more substances selected from the group consisting of~~: a) monoglyceride preparations having at least 80% monoglyceride content and having a formula



wherein R is selected from the group consisting of H and an acyl group containing from 6 to 24 carbon atoms with the *proviso* that two of the R groups are H and b) a fatty acid with 6 to 24 carbon atoms and ~~as immunizing component~~, and an immunogenic product consisting of antigenically active carbohydrate moieties (ACM) from *Mycobacterium tuberculosis* which are each covalently coupled, via divalent bridge groups, to immunologically active carriers (IAC).

34 (currently amended). An nose-drop package according to claim 29, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the ~~immunizing component~~ immunogenic product is lipoarabinomannan-tetanus toxoid (LAM-TT).

38 (currently amended). A method of vaccinating a mammal against a *Mycobacterium* ~~having antigenically active carbohydrate moieties (ACM) from Mycobacterium tuberculosis which comprises mucosa administration~~ comprising mucosally administering to the mammal ~~of~~ a protection-inducing amount of a ~~tuberculosis~~ vaccine formulation comprising ~~as~~ an adjuvant comprising ~~one or more substances selected from the group consisting of~~: a) monoglyceride preparations having at least 80% monoglyceride content and having a formula



wherein R is selected from the group consisting of H and an acyl group containing from 6 to 24 carbon atoms with the *proviso* that two of the R groups are H and b) a fatty acid with 6 to 24 carbon atoms and ~~as immunizing component,~~ and an immunogenic product consisting of antigenically active carbohydrate moieties (ACM) from *Mycobacterium tuberculosis* which are each covalently coupled, via divalent bridge groups, to immunologically active carriers (IAC).

40 (currently amended). The method of vaccinating a mammal against ~~mycobacterium~~ *Mycobacterium* according to claim 38, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms and the immunologically active carriers (IAC) are ~~derived~~ from polypeptide and are selected from the group consisting of tetanus toxoid, diphtheria toxoid, cholera subunit B or Protein D from *H. influenza*.

43 (currently amended). The method of vaccinating according to claim 38, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the ~~immunizing component~~ immunogenic product is lipoarabinomannan-tetanus toxoid (LAM-TT).

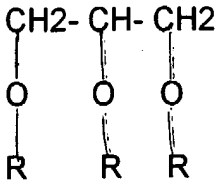
Claim 48. (currently amended) The ~~vaccine formulation~~ aerosol or spray package of claim 20, wherein the antigenically active carbohydrate moieties (ACM) are each covalently coupled via identical divalent bridge groups to the immunologically active carriers (IAC).

Claim 49. (currently amended) The ~~vaccine formulation~~ nose-drop package of claim 29, wherein the antigenically active carbohydrate moieties (ACM) are each covalently coupled via identical divalent bridge groups to the immunologically active carriers (IAC).

Claim 50. (currently amended) The ~~vaccine formulation~~ method of vaccinating of claim 38, wherein immunizing product consists of antigenically active carbohydrate moieties (ACM) are each covalently coupled via identical divalent bridge groups to the immunologically active carriers (IAC).

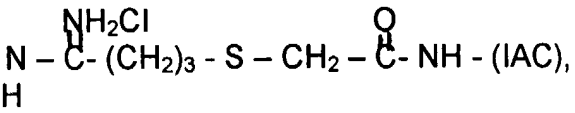
Clean Copy of Claims

1. A vaccine formulation against a *Mycobacterium* comprising an adjuvant comprising: a) monoglyceride preparations having at least 80% monoglyceride content and having a formula



wherein R is selected from the group consisting of H and an acyl group containing from 6 to 24 carbon atoms with the *proviso* that two of the R groups are H and b) a fatty acid with 6 to 24 carbon atoms and an immunogenic product consisting of antigenically active carbohydrate moieties (ACM) from *Mycobacterium tuberculosis* which are each covalently coupled, via divalent bridge groups, to immunologically active carriers (IAC).

2. The vaccine formulation according to claim 1, wherein the immunologically active carriers (IAC) contain amino groups and said divalent bridge group has the following structural formula



wherein LAM is Lipoarabinomannan.

3. The vaccine formulation according to claim 1, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90%, and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms, and the immunologically active carriers (IAC) are from polypeptides which are selected from the group consisting of tetanus toxoid, diphtheria toxoid, cholera subunit B and Protein D from *H. influenza.*

4. The vaccine formulation according to claim 3, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 14 to 20 carbon atoms, and the immunologically active carriers (IAC) are from polypeptides which are selected from the group consisting of tetanus toxoid, diphtheria toxoid, cholera subunit B and Protein D from *H. influenza.*

5. The vaccine formulation according to claim 1, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure controlling agents, carrier gases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters and anti-oxidative agents.

6. The vaccine formulation according to claim 1, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunogenic product is lipoarabinomannan-tetanus toxoid (LAM-TT).

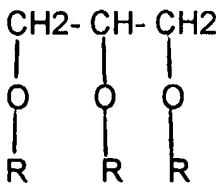
7. The vaccine formulation according to claim 6, wherein the adjuvant further comprises soybean oil.

8. The vaccine formulation according to claim 1, wherein the formulation is formulated into a preparation for mucosal administration.

9. The vaccine formulation according to claim 8, wherein the mucosal administration is for nasal, pulmonary, oral or vaginal administration.

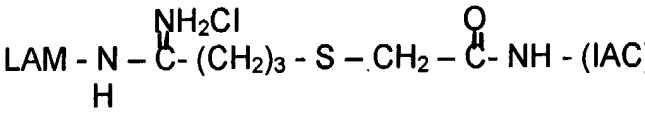
10. The vaccine formulation of claim 1, wherein the antigenically active carbohydrate moieties (ACM) are each covalently coupled via identical divalent bridge groups to the immunologically active carriers (IAC).

11. An aerosol or spray package comprising a vaccine formulation comprising an adjuvant comprising: a) monoglyceride preparations having at least 80% monoglyceride content and having a formula



wherein R is selected from the group consisting of H and an acyl group containing from 6 to 24 carbon atoms with the *proviso* that two of the R groups are H and b) a fatty acid with 6 to 24 carbon atoms and an immunogenic product consisting of antigenically active carbohydrate moieties (ACM) from *Mycobacterium tuberculosis* which are each covalently coupled, via divalent bridge groups, to immunologically active carriers (IAC).

12. An aerosol or spray package according to claim 11, wherein the immunologically active carriers (IAC) contain amino groups and said divalent bridge group has the following structural formula



wherein LAM is Lipoarabinomannan.

13. An aerosol or spray package according to claim 12, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90%, and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms, and the immunologically active carriers (IAC) are from polypeptide and are selected from the group consisting of tetanus toxoid, diphtheria toxoid, cholera subunit B and Protein D from *H. influenza*.

14. An aerosol or spray package according to claim 13, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 14 to 20 carbon atoms, and the immunologically active carriers (IAC) are from polypeptides which are selected from the group consisting of tetanus toxoid, diphtheria toxoid, cholera subunit B and Protein D from *H. influenza*.

15. An aerosol or spray package according to claim 12, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure controlling agents, carrier gases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoter and anti-oxidative agents.

16. An aerosol or spray package according to claim 12, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunogenic product is lipoarabinomannan-tetanus toxoid (LAM-TT).

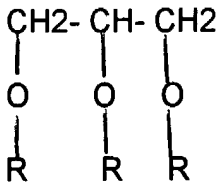
17. An aerosol or spray package according to claim 12, wherein the formulation is formulated into a preparation for mucosal administration.

18. An aerosol or spray package according to claim 17, wherein the mucosal administration is for nasal, pulmonary, oral or vaginal administration.

19. An aerosol or spray package according to claim 16, wherein the adjuvant further comprises soybean oil.

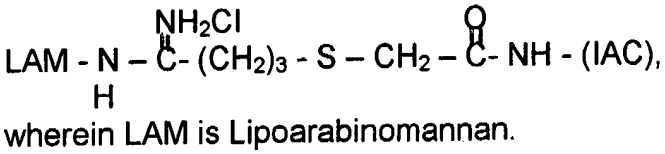
20. The aerosol or spray package of claim 11, wherein the antigenically active carbohydrate moieties (ACM) are each covalently coupled via identical divalent bridge groups to the immunologically active carriers (IAC).

21. A nose-drop package comprising a vaccine formulation comprising an adjuvant comprising: a) monoglyceride preparations having at least 80% monoglyceride content and having a formula



wherein R is selected from the group consisting of H and an acyl group containing from 6 to 24 carbon atoms with the *proviso* that two of the R groups are H and b) a fatty acid with 6 to 24 carbon atoms and an immunogenic product consisting of antigenically active carbohydrate moieties (ACM) from *Mycobacterium tuberculosis* which are each covalently coupled, via divalent bridge groups, to immunologically active carriers (IAC).

22. An nose-drop package according to claim 21, wherein the immunologically active carriers (IAC) contain amino groups and said divalent bridge group has the following structural formula



wherein LAM is Lipoarabinomannan.

23. An aerosol or spray package according to claim 21, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90%, and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms, and the immunologically active carriers (IAC) are from polypeptide and are selected from the group consisting of tetanus toxoid, diphtheria toxoid, cholera subunit B and Protein D from *H. influenza.*

24. An aerosol or spray package according to claim 23, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95%, and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms, and the immunologically active carriers (IAC) are from polypeptide and are selected from the group consisting of tetanus toxoid, diphtheria toxoid, cholera subunit B and Protein D from *H. influenza.*

25. An nose-drop package according to claim 21, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure controlling agents, carrier gases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoter and anti-oxidative agents.

26. An nose-drop package according to claim 21, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunogenic product is lipoarabinomannan-tetanus toxoid (LAM-TT).

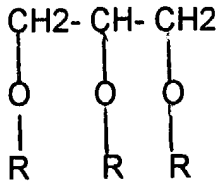
27. An nose-drop package according to claim 21, wherein the formulation is formulated into a preparation for mucosal administration.

28. An nose-drop package according to claim 21, wherein the mucosal administration is for nasal, pulmonary, oral or vaginal administration.

29. An nose-drop package according to claim 26, wherein the adjuvant further comprises soybean oil.

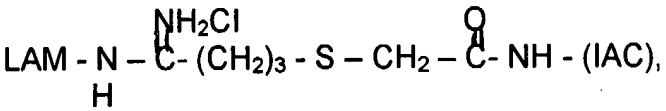
30. The nose-drop package of claim 21, wherein the antigenically active carbohydrate moieties (ACM) are each covalently coupled via identical divalent bridge groups to the immunologically active carriers (IAC).

31. A method of vaccinating a mammal against a *Mycobacterium* comprising mucosally administering to the mammal a protection-inducing amount of a vaccine formulation comprising an adjuvant comprising: a) monoglyceride preparations having at least 80% monoglyceride content and having a formula



wherein R is selected from the group consisting of H and an acyl group containing from 6 to 24 carbon atoms with the *proviso* that two of the R groups are H and b) a fatty acid with 6 to 24 carbon atoms and an immunogenic product consisting of antigenically active carbohydrate moieties (ACM) from *Mycobacterium tuberculosis* which are each covalently coupled, via divalent bridge groups, to immunologically active carriers (IAC).

32. An nose-drop package according to claim 31, wherein the immunologically active carriers (IAC) contain amino groups and said divalent bridge group has the following structural formula



wherein LAM is Lipoarabinomannan.

33. The method of vaccinating according to claim 31, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90%, and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms, and the immunologically active carriers (IAC) are from polypeptide and are selected from the group consisting of tetanus toxoid, diphtheria toxoid, cholera subunit B and Protein D from *H. influenza.*

34. The method of vaccinating according to claim 31, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95%, and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms, and the immunologically active carriers (IAC) are from polypeptide and are selected from the group consisting of tetanus toxoid, diphtheria toxoid, cholera subunit B and Protein D from *H. influenza.*

35. The method of vaccinating according to claim 31, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure controlling agents, carrier gases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoter and anti-oxidative agents.

36. The method of vaccinating according to claim 31, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunogenic product is lipoarabinomannan-tetanus toxoid (LAM-TT).

37. The method of vaccinating according to claim 31, wherein the formulation is formulated into a preparation for mucosal administration.

28. The method of vaccinating according to claim 31, wherein the mucosal administration is for nasal, pulmonary, oral or vaginal administration.

39. The method of vaccinating according to claim 37, wherein the adjuvant further comprises soybean oil.

40. The method of vaccinating according to claim 31, wherein the antigenically active carbohydrate moieties (ACM) are each covalently coupled via identical divalent bridge groups to the immunologically active carriers (IAC).